K012604

APR 1 9 2002

Section 2
510(k) Summary

Submitter's name and Address:	ClearMedical, Inc. 1776 – 136th Place NE Bellevue, WA 98005 Ph (425) 401-1414 Fax (425) 401-1515
FDA Registration Number:	3017110
Contact Person:	Richard Radford Director of Research and Product Development (425) 401-1414
Date Summary Prepared:	August 8, 2001
Trade or Proprietary Name:	ClearMedical/RADI FemoStop Femoral Compression System
Common Name:	Clamp, Vascular
Classification Name:	Vascular Clamp (per 21 CFR section 870.4450)/DXC

Equivalent Device

The reprocessed ClearMedical/RADI FemoStop Femoral Compression System is substantially equivalent to the RADI FemoStop Femoral Compression System. This determination has been reached based on an evaluation and analysis of the predicate device's technical and promotional labeling and specific bench testing. For all established indicators of substantial equivalence, the ClearMedical devices demonstrated equality in safety and performance.

Device Description:

The ClearMedical/RADI FemoStop Belt and Arch are accessory devices to a FemoStop Femoral Compression System which is used for the compression of the femoral artery or vein after catheterization.

The FemoStop Arch is designed with an inflatable pneumatic bladder that fills with air to provide compression to the femoral artery or vein. A connector element attaches the FemoStop Arch to the FemoStop Pump. The ClearMedical/RADI FemoStop adds a transparent Sterile 2 mil Polyethylene Dome cap to provide a sterile barrier between the patient and the FemoStop Dome.

The FemoStop Arch and Belt are latex-free. The Arch is made of methyl butadiene styrene, with an ethylene vinyl acetate bladder. The Belt is made of polyester. The Arch is designed with polyethylene tubing and a polycarbonate luer-lock connector.

Intended Use:

The reprocessed ClearMedical/RADI FemoStop is intended as a single patient use accessory to a RADI Reusable FemoStop Pump. The role of the FemoStop is to provide compression of the femoral artery or vein after catheterization. The FemoStop is used in conjunction with the FemoStop Pump in a hospital environment.

Technological Characteristics of ClearMedical and Predicate Devices:

The predicate device and the ClearMedical/RADI FemoStop each contain an inflatable pneumatic bladder that fills with air to provide compression to the femoral artery or vein after catheterization. Attached to the Arch is a connector tubing system that connects to the FemoStop Pump. In form, the predicate device and the ClearMedical reprocessed device are nearly identical.

The predicate device is delivered to the customer labeled 'sterile' whereas the ClearMedical/RADI FemoStop is delivered to the customer labeled "High Level-Disinfected." The ClearMedical/RADI devices include a transparent sterile domecap to be placed over the bladder of the arch as a sterile interface at the patient wound site.

Summary of ClearMedical/RADI FemoStop Performance:

Based on an assessment of bench tests and non-clinical performance data, we believe that in all relevant safety and performance indicators the ClearMedical/ RADI FemoStop Arch, Dome, Belt, Tubing and Sterile Dome Pressure Cover demonstrate substantial equivalence to the predicate's device, the RADI FemoStop Arch, Dome, Belt, Tubing and Sterile Dome Pressure Cover.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 9 2002

Mr. Richard Radford
Director of Research and Product Development
ClearMedical, Inc.
1776 - 136th Place NE
Belluvue, WA 98005

Re: K012604
Trade Name: ClearMedical/RADI FemoStop Femoral Compression System
Regulation Number: 21 CFR 870.4450
Regulation Name: Clamp, Vascular
Regulatory Class: Class II (two)
Product Code: DXC
Dated: January 18, 2002
Received: January 22, 2002

Dear Mr. Radford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(K) NUMBER (IF KNOWN): K012604

DEVICE NAME: ClearMedical/RADI Medical Systems FemoStop
Femoral Compression System

INDICATIONS FOR USE:

The ClearMedical/RADI FemoStop femoral compression system is indicated in the compression of the femoral artery or vein after catheterization.

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012604

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)